PEVO			AF/3743	
FEB 2 3 2004 FRANS	MITTAL OF APPEAL BR	IEF (Large Entity)	Dőcket No. ( 2035.733	
In Propin Ion Of: RI	CHARD WISNIEWSKI		H	
Serial No. 09/579,846	Filing Date MAY 25, 2000	Examiner JOHN K. FORD	Group Art Unit 3743	
Invention: ENHANCED	THAWING OF BIOPHARMA	CUETICAL SOLUTIONS USING O	SCILLATORY MOTION	
	TO THE COMMISS	IONER FOR PATENTS:		
Transmitted herewith in tr	iplicate is the Appeal Brief in this	s application, with respect to the No	tice of Appeal filed on	
The fee for filing this Appe	eal Brief is: \$330.00			
A check in the am	ount of the fee is enclosed.			
The Director has a	Iready been authorized to charg	ge fees in this application to a Depos	sit Account.	
	eby authorized to charge any fe posit Account No. 08-1935	es which may be required, or credit	any	
		RE	RECEIVED	
• 1			MAR 0 1 2004	
	(	•	DLOGY CENTER R3700	
- Vat H si	gnature gnature	Dated: February 18, 2004	_	
VICTOR A. CARDONA, Attorney for Applicant - F				
	FARLEY & MESITI P.C.	on 02/ <u>76</u> /2004 first class mail under 37 C Commissioner for Patents 22313-1450.	nent and fee is being deposited with the U.S. Postal Service as C.F.R. 1.8 and is addressed to the s, P.O. Box 1450, Alexandria, VA	
			R A. CARDONA	
CC:			of Person Mailing Correspondence	

È

Docket No. 2035.733 Filed: May 26, 2000

# **W THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Apple ant:	Richard Wisniewski	Confirmation No.:	8512
Serial No.:	09/579,846	Group Art Unit:	3743
Filed:	May 25, 2000	Examiner:	John K. Ford

Title:

ENHANCED THAWING OF BIOPHARMACEUTICAL SOLUTIONS USING OSCILLATORY MOTION

## **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February [20], 2004.

Victor A. Cardona, Esq. Attorney for Applicant Registration No. 44,589

Date of Signature: February 10, 2004

To: Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 RECEIVED

MAR 0 1 2004 TECHNOLOGY CENTER R3700

# APPELLANT'S APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

## Dear Sir:

This is an appeal under 37 C.F.R. § 1.191 and § 1.192 from a final Office Action dated September 29, 2003, of claims 2, 3, 6-9, and 18-21, comprising all the claims finally rejected. A Notice of Appeal was timely filed on December 22, 2003. This Appeal Brief is therefore filed within two months, i.e., by February 22, 2004. A Transmittal of Appeal Brief is included herewith along with a check in the amount of **\$160.00**, as set forth in 37 C.F.R. § 1.17(f).

02/26/2004 JADDO1 00000096 09579846 01 FC:1402 330.00 DP

•

Docket No. 2035.733 Filed: May 26, 2000

## **REAL PARTY IN INTEREST**

Integrated Biosystems, Inc., the assignee of all the inventors' rights in this patent application, is the real party in interest.

## **RELATED APPEALS AND INTERFERENCES**

To the knowledge of the Appellants, Appellants' undersigned legal representative, and the assignee, there are no appeals or interferences, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

# **STATUS OF CLAIMS**

Claims 1-17 were originally presented in the subject application. An amendment filed on November 5, 2001 added new claim 18, canceled claim 1, and amended claims 2-11. An amendment filed February 19, 2002 amended claim 18. Claim 18 was amended, new claims 19-21 were added, and claims 4, 5 and 10-17 were cancelled in an amendment dated on January 2, 2003. In a response dated June 25, 2003, claims 18-21 were amended.

## **STATUS OF AMENDMENTS**

No amendments were filed subsequent to the Final Office Action dated September 29, 2003.

## SUMMARY OF INVENTION

In a first aspect of the invention, a method for thawing a frozen biopharmaceutical solution includes heating the biopharmaceutical solution, when at least a portion of the biopharmaceutical solution is frozen, using a heating element (pages 10-11, 15) coupled to a

Docket No. 2035.733 Filed: May 26, 2000

container (102, FIG. 1; page 5) which contains the biopharmaceutical solution. An oscillatory motion is induced to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution using a oscillatory driver (104, 106, FIG. 1; page 5, 13) adapted to be coupled to the biopharmaceutical solution. The driver inducing the oscillatory motion rolls the container from a first position to a second position along, and in contact with, a surface, and the driver rolls the container a distance from the second position toward the first position along, and in contact with, the surface.

In a second aspect of the invention, a method for thawing a frozen biopharmaceutical solution includes heating the biopharmaceutical solution held in a container (102, FIG. 1; page 5), when at least a portion of the biopharmaceutical solution is frozen. The container is moved from a first position to a second position along, and in contact with, a surface, wherein the first position and the second position are separated by a distance along the surface. The container is moved a second distance from the second position toward the first position along, and in contact with, the surface.

In a third aspect of the invention, a method for thawing a frozen biopharmaceutical solution includes heating the biopharmaceutical solution held in a container (102, FIG. 1, page 5), when at least a portion of the biopharmaceutical solution is frozen. The container is operatively moved from a first position to a second position along, and in contact with, a surface using a motor driving a linkage (page 13) wherein the first position and the second position are separated by a distance along the surface. The container is moved a second distance from the second position toward the first position, along, and in contact with, the surface.

In a fourth aspect of the invention, a method for thawing a frozen biopharmaceutical solution includes heating the biopharmaceutical solution held in a container (102, FIG. 1, page 5), when at least a portion of the biopharmaceutical solution is frozen. The method further includes a step for moving the container from a first position to a second position along, and in contact with, a surface, wherein the first position and the second position are separated by a distance along the surface. Also included is a step for moving the container a second distance from the second position toward the first position along, and in contact with, the surface.

Docket No. 2035.733 Filed: May 26, 2000

. .\*

## **ISSUES**

×,

1. Whether claims 2, 3, 6-9, and 18-21 comply with the written description requirement under 35 U.S.C. §112, first paragraph.

2. Whether claims 2, 9, and 18-21 are obvious over the article entitled Large-scale Freezing and Thawing Biopharmaceutical Drug Products by Wu and Wisniewski dated 1992 in view of either Japanese Reference No. 63-296,831.

3. Whether claims 2, 9, and 18-21 are obvious over the article entitled Large-scale Freezing and Thawing Biopharmaceutical Drug Products by Wu and Wisniewski dated 1992 in view of either Japanese Reference No. 2-187,138.

4. Whether claims 2, 9, and 18-21 are obvious over the article entitled Large-scale Freezing and Thawing Biopharmaceutical Drug Products by Wu and Wisniewski dated 1992 in view of either Japanese Reference No. 2-261,371.

٦

- -

# **GROUPING OF CLAIMS**

With respect to each of the issues on appeal recited above, Appellants believe each of the following claim sets to be separately patentable over the prior art cited in the §103 rejection thereof:

Claims 2-3, 6-9, and 18 (i.e., claims 2-3 and 6-9 stand or fall with claim 18);

Claim 19;

Claim 20; and

Claim 21.

## ARGUMENTS

## 1. § 112 Rejections

The Final Office Action rejects claims 2, 3, 6-9 and 18-21 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action alleges that the container recited in claims 18-21 cannot roll or otherwise move along a surface by itself and instead rolls on wheels or rollers. Therefore, it is alleged that these claims do not comply with the written description since there is no support in the specification, claims, or drawing figures for a container which itself rolls along, and in contact with, the surface.

The standard for an adequate written description to support a particular claim turns on whether a person of ordinary skill in the art is able to recognize that what has been claimed has been invented by the applicant. Further, the written description requirement can be satisfied by a drawing if the subject matter claimed would be understood to one skilled in the art from the drawing and description. Moreover, the drawings alone may satisfy this requirement. See <u>Vas-Cath Inc. v. Mahurkar</u>, 19 U.S.P.Q.2d at 1116-1118 (Fed. Cir. 1991).

Page 5 of the present application describes a wheeled container 102, and FIG. 1 depicts container 102 having wheels on a bottom portion thereof. The container clearly rolls along the surface depicted in FIG. 1, particularly considering the description on page 5 of wheeled container 102 and such container having drivers inducing oscillatory motion to frozen biopharmaceutical material within such a container. The Office Action alleges that one of ordinary skill in the art would not be able to recognize that container 102 rolls on wheels. Instead, the Office Action appears to allege that container 102 does not itself roll along a surface and instead it rolls on wheels or rollers. Such argument would be akin to a car not rolling from one place to another but instead one describing that wheels of a car roll from place to place.

The Merriam-Webster on-line dictionary (www.com) defines "roll" in several ways. One such definition is "to move on rollers or wheels" (see definition 4 in Appendix B). Although

other definitions are presented (see Appendix B), the description in the specification on page 5, which describes a wheeled container and the depiction in FIG. 1 of a container on a surface, makes the use of this definition appropriate. Objects are often described as rolling on a surface without the entire object actually turning over and over on the surface (see definition 1 in Appendix B) as the Office Action appears to allege, e.g. a car is said to roll along a road without the roof of the car and bottom of the car actually turning over repeatedly on such road. It is respectfully submitted that one of ordinary skill in the art, upon reading the recitation of the container being rolled from a first position to a second position along, and in contact with, a surface and the description on page 5 of a wheeled container and oscillation drivers, would understand that the container includes wheels or other means which allow it to roll or move in the specified manner. Thus, it is respectfully submitted that these claims overcome the § 112 rejection.

## 2. Wisniewski and Wu Article in View of Japanese Reference No. 63-246,831

The Final Office Action rejects claims 2, 9, and 18-21 under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of Japanese Reference No. 63-296,831. Specifically, the Office Action alleges that the Wisniewski and Wu article teaches a shaker platform and heater. Japanese Reference '831 is alleged to disclose a shaker platform, which allows a table to oscillate by moving back and forth on rollers. Further, the Office Action alleges that it would have been obvious to oscillate the tank disclosed in the Wisniewski and Wu article back and forth on rollers to effect faster thawing of the biopharmaceutical materials. The Office Action also alleges that the shaker platforms are virtually ubiquitous in biochemical and biomedical laboratories.

Claim 18 recites a method for thawing a frozen biopharmaceutical solution which includes heating the biopharmaceutical solution, when at least a portion of the biopharmaceutical solution is frozen. The heating is performed using a heating element coupled to a container, which contains the biopharmaceutical solution. Oscillatory motion is induced to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution using

an oscillatory driver adapted to be coupled to the biopharmaceutical solution. The driver inducing the oscillatory motion rolls the container from a first position to a second position along, and in contact with, a surface, and the driver rolls the container a distance from the second position toward the first position along, and in contact with, the surface.

The Wisniewski and Wu article discloses a mechanical shaker platform being used to provide agitation during thawing (see page 134, col. 3, fourth full paragraph). However, there is no disclosure, teaching, or suggestion of a container holding biopharmaceutical solution being rolled along, and in contact with, a surface from a first position to a second position. Further, there is no teaching, disclosure, or suggestion of a container holding a biopharmaceutical solution being rolled a distance from the second position toward the first position along, and in contact with, the surface. Instead, the Wisniewski and Wu reference merely discloses a shaker table providing agitation during thawing, but any container located on a shaker table would be stationary relative to such shaker table during movement thereof. In this manner, any movement generated by a shaker table would be transferred to the contents of the container and not the container itself.

Even if a container situated on a shaker table did move relative to the shaker table, the container could not be considered to roll from a first position to a second position, nor to roll from the second position toward the first position, as recited in claim 18. In particular, the tank disclosed in Wisniewski and Wu article does not roll since the article merely states that agitation may be provided upon a mechanical shaker platform. There is no indication that such a tank would be capable of rolling and in fact, if it was capable of rolling, it would likely roll off such a shaker platform as soon as the platform was turned on and began to shake the tank. Such tank would not then roll from the first position to a second position and from the second position toward the first position, as recited in claim 18, since it would be thrown from such shaker table without the possibility of it returning toward an original position (i.e., the first position). Accordingly, this reference cannot disclose the rolling of the container. Thus, the Wisniewski and Wu article does not disclose a container holding biopharmaceutical material which rolls along, and in contact with, a surface from a first position to a second position, nor rolling the

container from the second position toward the first position along, and in contact with, the surface.

Japanese Reference No. 63-296,831 discloses a shaker table which may roll in one direction on a supporting truck movable in a second direction. However, there is no disclosure of a container holding biopharmaceutical material being rolled along, and in contact with, a surface from a first position to a second position, and the container being rolled a distance from the second position toward the first position along, and in contact with, the surface. Instead, the platform appears to be movable by a linkage in one direction and to be capable of rolling in a second direction with a specimen being placed on the platform, but there is no indication of the container rolling.

As described above, the Office Action alleges that the tank of Wisniewski and Wu may be oscillated back and forth on the rollers of Reference' 831. Any rolling disclosed in this reference occurs between the platform and the rollers supporting such platform and between the rollers and the surface upon which such rollers are received. However, there is no disclosure, teaching or suggestion of rolling or movement between a tank received on the platform and the platform itself. The platform moves, and the rollers move, but the tank does not move relative to a surface (e.g., the platform). A container or tank received on the platform would be movable along with such movable platform but the container would be stationary relative to the platform itself during any such movement. Thus, the container would not roll, nor would it be rolled along, and in contact with, a surface, as recited in claim 18. Moreover, such a container would not roll from a first position to a second position, nor would it roll from the second position toward the first position along, and in contact with, the surface, as also recited in claim 18. Accordingly, Reference' 831 does not disclose rolling of the container, and instead it discloses the rolling of a platform and the rolling of rollers. Reference' 831 does not disclose the movement or rolling of the container along, and in contact with, a surface, and instead any container received on the platform of Reference'831 is stationary relative to the platform on which it is received. There is also no disclosure of movement of the container from a first position to a second position, nor movement from the second position toward the first position.

Further, even if a container did move relative to the platform in the device disclosed in Reference '831, it would not roll nor would it move from a first position to a second position and from a second position toward the first position. As described above, if a container positioned on the platform in Reference '831 included wheels, it would likely be thrown from the surface of the platform as soon as the platform started to move. Further, if the container moved or rolled relative to the platform, there is no indication that it would move from a first position to a second position and then from that second position toward the first position. Instead, if the container did move relative to the platform, such motion would be random and could result in such container being thrown from the platform and would not result in the movement recited in claim 18.

Thus, a combination of Wisniewski and Wu with Japanese Reference No. 63-296,831, could not result in claim 18 of the present application because there is no disclosure in either of these references of a container which contains biopharmaceutical material being rolled along, and in contact with, a surface from a first position to a second position, and the container being rolled from the second position toward the first position along, and in contact with, the surface. Further, even if the references were combined as suggested in the Office Action, i.e., the tank of Wisniewski and Wu was oscillated on the rollers of Reference '831, the features of claim 18 as described would not result, because the container would be stationary relative to the surface on which it would be received and it would not roll. Even if the container did roll, it would roll off the surface of such platform or would roll from one position. Therefore, because the subject matter of claim 18 of the present application is not disclosed, taught, or suggested by the combination of the Wisniewski and Wu article and Japanese Reference No. 63-296,831, claim 18 is believed not to be obvious over such references.

Also, the Office Action does not even allege that all the elements of the independent claims are disclosed by the cited references. Specifically, the Office Action does not allege that a container would move or roll from a first position to a second position along, and in contact with a surface, nor that such container would move from the second position toward the first position. Therefore, because the Office Action does not even allege that the cited references

7

disclose all the features of the independent claims, a combination of the cited references cannot make such independent claims obvious.

The Office Action also alleges that a container situated on a shaker platform would move back and forth on rollers of the platform as the platform moved. Accordingly, the Office Action appears to allege that the container rolls on rollers despite the fact that it sits on a platform which is alleged to roll on such rollers, while the container remains stationary relative to such platform. In other words, the container is alleged to roll because the platform on which it sits is alleged to roll, but there is no allegation that the container itself rolls on such rollers or that the container rolls on the surface on which it is received. This contrasts with the allegation in the Office Action that container 102 cannot be considered to roll, as recited in claim 18, since FIG. 1 depicts such container having wheels upon which the container rolls, i.e., the wheels are alleged to roll and not the container. Thus, the Office Action appears to allege that a container may roll on a platform, even though the container does not actually contact the rollers, but that container 102 does not roll because wheels thereof do the rolling. It is respectfully submitted that these allegations present inconsistent positions.

Further, the other independent claims (i.e., claims 19-21) recite, inter alia, a container, which is moved from a first position to a second position along, and in contact with, a surface, and the container being moved from the second position toward the first position, along, and in contact with, the surface. The first position and second position are separated from each other by a distance along the surface. Similar to the discussion above regarding claim 18, the combination of references do not teach, disclose or suggest a container which is moved as recited in these claims. Specifically, the shaker table disclosed in Wisniewski and Wu, nor that disclosed in Ref. '831, disclose movement of a container from a first position to a second position and from the second position toward the first position, with such movement being along, and in contact with, a surface. Further, there is no disclosure of such a first position and second position being separated from each other by a distance along the surface, sor relating to claim 20 there is no disclosure of such container being moved in such a manner using a motor driving a linkage.

Also, there is no allegation in the Office Action that the cited references teach such movement of a container. Instead, the Office Action merely alleges that the tank in the Wisniewski and Wu reference contains biopharmaceutical material, that such tank is located on a shaker table which may agitate the tank, and further that the platform of such reference may move back and forth on rollers of such a shaker table. However, there is no allegation of a container being moved from a first position to a second position and from the second position toward the first position, nor such first and second positions being separated by a distance. Accordingly, independent claims 19-21 are believed not to be obvious and are believed to be allowable.

## 3. Wisniewski and Wu Article in View of Japanese Reference No. 2-187,138

The Final Office Action rejected claims 2, 9, and 18-21 under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of Japanese Reference No. 2-187,138. As described above, the Office Action alleges that the Wisniewski and Wu article teaches a shaker platform and heater.

Reference '138 is alleged to disclose a shaker platform having rollers which roll in contact with tracks (alleged to be surfaces) allegedly depicted in FIG. 5. However, this reference is not alleged to disclose a container which moves or rolls along, and in contact with, a surface. Instead, the platform itself is alleged to roll as opposed to a container rolling. Accordingly, these references cannot disclose the subject matter recited in claims 18-21 of the present application, which recite containers rolling or moving along, and in contact with a surface, from a first position to a second position and from a second position toward the first position.

Reference '138 discloses a shaker table having an eccentric rotary shaft and two movable plates for moving a shaking stand or platform mounted of the top of such plates. However, there is no disclosure of a container of biopharmaceutical material being rolled along, and in contact with, a surface. Instead, the platform in Reference '138 may receive a specimen, but such specimen would move back and forth with, and would remain stationary relative to, the platform. This is in contrast to the movement (i.e., rolling) of the container along, and in contact with, a

۶

surface, recited in claim 18 of the present application. Further, the suggested combination of Wisniewski and Wu with Reference '138 would also not result in claim 18 of the present application since neither Wisniewski and Wu, nor Reference '138, disclose a container rolling or moving along, and in contact with, a surface from a first position to a second position, and the container being moved along, and in contact with, the surface from the second position toward the first position. More specifically, oscillation of the container of Wisniewski and Wu on the device of Reference '138 would not result in the subject matter recited in claim 18 of the present application because the container of Wisniewski and Wu would be stationary relative to the surface on which it would be received and thus could not be moved in the manner recited in claim 18.

Further, as noted above regarding the Reference '831, a container placed on the platform of Reference '138 would likely be thrown from such a moving platform if it were allowed to roll. Even if the container oscillating on the device in Reference '138 did move relative thereto without being thrown off, there is no indication that such container would move from a first position to a second position and from a second position toward a first position along, and in contact with, a surface.

Moreover, although the Office Action alleges that Reference' 138 shows a shaker platform having rollers which roll in contact with tracks (which are alleged to be surfaces), the rolling of such rollers does not disclose a container rolling along, and a contact with a surface from a first position to a second position and from the second position toward the first position. More specifically, the rollers may roll in contact with tracks, and the plates may move relative to one another, but the container remains stationary and does not roll relative to a surface, e.g., the surface upon which it is received. Accordingly, this reference does not disclose a container rolling along, and in contact with, a surface from a first position to a second position and from the second position toward the first position. Therefore, claim 18 is believed not to be obvious over this combination of references.

Also, claims 19-22 are believed not to be obvious for the same reasons described above relative to claim 18 regarding the lack of a teaching, suggestion, or motivation for the movement

•

of a container along, and in contact with, a surface from a first position to a second position and from the second position toward the first position. Further, claim 20 recites the additional feature of a container being moved using a motor driving a linkage. Claims 19-21 further recite the first position and a second position being separated by a distance along the surface. Thus, these claims are believed to be allowable for the same reasons described for claim 18 regarding movement of the container along, and in contact with, the surface from the first position to the second position toward the first position, and for their own additional features. The dependent claims are believed not to be obvious for these reasons and for their own additional features. Thus, the independent and dependent claims are believed to be allowable.

# 4. Wisniewski and Wu Article in View of Japanese Reference No. 2-261,371

Claims 2, 9, and 18-21 have been rejected under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of Japanese Reference No. 2-261,371. As described above, the Wisniewski and Wu article is alleged to teach a shaker platform and Reference No. '371 is alleged to disclose a motor driven linkage for reciprocal shaking in an "X" direction. Rollers thereof are alleged to roll along a surface. Further the Office Action alleges that it would have been obvious to oscillate the tank disclosed in the Wisniewski and Wu article back and forth on rollers to effect faster thawing of the biopharmaceutical material as described above.

As described in Sections 2 and 3 above, the shaker table disclosed in reference '371 does not disclose a container being rolled along, and in contact with, a surface. Such container remains stationary relative to such shaker table to allow the contents thereof to be agitated. In the event the container did move relative to the platform, there is no indication that it would move from a first position to a second position and then from the second position toward the first position along, and in contact with, the surface. Moreover, it is likely that a moving container would be thrown from such platform and therefore would not move from the first position to the second position and from the second position toward the first position. Accordingly, the combination of the Wisniewski and Wu article and reference '371 cannot make claim 18 of the

ş

<u>•</u>!

present application obvious. The dependent claims are believed not to obvious for the same reasons and for their own additional features.

Independent claims 19-21 are believed not to be obvious for the same reasons as claim 18 relative to the movement of the container and for their additional features. For example, claims 19-21 recite the first position and the second position being separated by a distance along the surface. Also, claim 20 recites the container being moved using a motor driving a linkage.

Docket No. 2035.733 Filed: May 26, 2000

## CONCLUSION

In conclusion, Appellant submits that claims 2, 3, 6 and 9, 18-21 are supported by the specification and are not improper under 35 U.S.C. § 112, first paragraph. Further it is respectfully submitted that claims 2, 9, and 18-21 are not obvious over the 1992 Wisniewski and Wu article in view of Japanese Reference No. 63-296,831, Japanese Reference No. 2-187,138 or Japanese Reference No. 2-261,371. Therefore, Appellant submits that the Final Office Action should be reversed in all respects.

Respectfully submitted,

Victor A. Cardona, Esq. Attorney for Appellants' Reg. No. 44,589

Dated: February <u>18</u>, 2004

Facsimile: (518) 452-5579

HESLIN ROTHENBERG FARLEY & , P.C. 5 Columbia Circle Albany, NY 12203-5160 Telephone: (518) 452-5600

i,

# Appendix A

 (Cancelled) A method for thawing frozen biopharmaceutical solutions comprising: providing a container that contains a biopharmaceutical solution, at least a portion of the biopharmaceutical solution being frozen,

providing an oscillatory driver coupled to the biopharmaceutical solution; providing a heat flux into the biopharmaceutical solution; and including oscillatory motion of the biopharmaceutical solution via oscillatory motion of the oscillatory driver to accelerate thawing, compared to motionless thawing, of the portion of the biopharmaceutical solution that is frozen.

2. *(Previously Presented)* The method of claim 18, wherein the oscillatory motion of the oscillatory driver is harmonic motion.

3. *(Previously Presented)* The method of claim 18, wherein the oscillatory motion of the oscillatory driver is disharmonic motion.

4. *(Cancelled)* The method of claim 18, wherein an amplitude of the oscillatory motion of the oscillatory driver ranges from about 0.0002 mm to about 10,000 mm.

5. *(Cancelled)* The method of claim 2, wherein an amplitude of the oscillatory motion of the oscillatory driver ranges from about 0.015 mm to about 350 mm.

6. *(Previously Presented)* The method of claim 18, wherein a frequency of the oscillatory motion of the oscillatory driver ranges from about 0.01 Hz to about 20 GHz.

7. (Original) The method of claim 4, wherein a frequency of the oscillatory motion of the oscillatory driver ranges from about 0.1 Hz to about 1 kHz.

8. (Original) The method of claim 5, wherein a frequency of the oscillatory motion of the oscillatory driver ranges from about 0.4 Hz to about 40 Hz.

Ą

١,

9. *(Previously Presented)* The method of claim 18, wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of the container.

10. *(Cancelled)* The method of claim 18, wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of the portion of the biopharmaceutical solution that is frozen.

11. *(Cancelled)* The method of claim 18, wherein the oscillatory motion of the oscillatory driver is induced by inducing oscillatory motion of an unfrozen portion of the biopharmaceutical solution.

12. *(Cancelled)* A device for accelerated thawing of a biopharmaceutical solution comprising

a container configured to contain the biopharmaceutical solution, where at least a portion of the biopharmaceutical solution is frozen;

a heating element, coupled to the container, that provides heat flux into the container; and

an oscillatory driver capable of being coupled to the biopharmaceutical solution, for inducing oscillatory motion of the biopharmaceutical solution to accelerate thawing, compared to motionless thawing, of the portion of the biopharmaceutical solution that is frozen.

13. (Cancelled) The device of claim 12, wherein the container comprises a thermal jacket.

14. (Cancelled) The device of claim 12, wherein the container comprises an agitator.

15. *(Cancelled)* The device of claim 12, wherein the oscillatory driver is mechanically coupled to the container.

1

1.

16. *(Cancelled)* The device of claim 12, wherein the oscillatory driver is magnetically coupled to the container.

17. *(Cancelled)* The device of claim 12, wherein the oscillatory driver is coupled to an internal structure, and the internal structure is located internally to the container.

18. *(Previously Presented)* A method for thawing a frozen biopharmaceutical solution, the method comprising:

heating the biopharmaceutical solution, when at least a portion of the biopharmaceutical solution is frozen, using a heating element coupled to a container which contains the biopharmaceutical solution; and

inducing oscillatory motion to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution using an oscillatory driver adapted to be coupled to the biopharmaceutical solution; and

wherein the driver inducing the oscillating motion rolls the container from a first position to a second position along, and in contact with, a surface, and the driver rolls the container a distance from the second position toward the first position along, and in contact with, the surface.

19. (*Previously Presented*) A method for thawing a frozen biopharmaceutical solution, the method comprising:

heating the biopharmaceutical solution held in a container, when at least a portion of the biopharmaceutical solution is frozen;

moving the container from a first position to a second position along, and in contact with, a surface wherein the first position and the second position are separated by a distance along the surface; and

moving the container a second distance from the second position toward the first position along, and in contact with, the surface.

20. (*Previously Presented*) A method for thawing a frozen biopharmaceutical solution, the method comprising:

•}

ŧ.

heating the biopharmaceutical solution held in a container, when at least a portion of the biopharmaceutical solution is frozen;

operatively moving the container from a first position to a second position along, and in contact with, a surface using a motor driving a linkage wherein the first position and the second position are separated by a distance along the surface; and

moving the container a second distance from the second position toward the first position along, and in contact with, the surface.

21. (*Previously Presented*) A method for thawing a frozen biopharmaceutical solution, the method comprising:

heating the biopharmaceutical solution held in a container, when at least a portion of the biopharmaceutical solution is frozen;

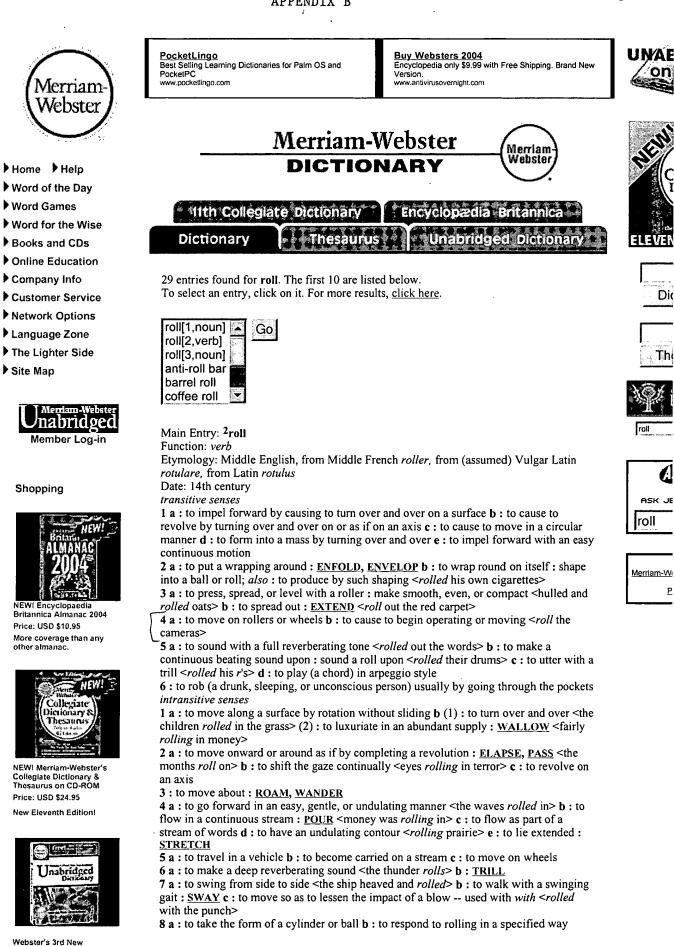
step for moving the container from a first position to a second position along, and in contact with, a surface, wherein the first position and the second position are separated by a distance along the surface; and

step for moving the container a second distance from the second position toward the first position along, and in contact with, the surface.

Merriam-Webster OnLine

ų<sup>ą</sup>

## APPENDIX B



## Merriam-Webster OnLine

International Dictionary on CD-ROM Price: USD \$69.95 You save 15%!

Visit Britannica Store

<b>9</b> a : to get under way : begin to move or operate b : to move forward : develop and maintain impetus; <i>especially</i> : to proceed or progress with notable ease or success < the
team was rolling>
10 a : BOWL b : to execute a somersault
11 of a football quarterback : to run toward one flank usually parallel to the line of
scrimmage especially before throwing a pass often used with out
- roll the bones : to shoot craps

Get the Top 10 Search Results for "roll"

For More Information on "roll" go to Britannica.com

Find <u>Photos, Magazines and Newspaper Articles about "roll"</u> at eLibrary. Free registration required.

- New site especially for Collegiate® Dictionary users Access all the latest words and meanings from the new Eleventh Edition of Merriam-Webster's Collegiate Dictionary! Learn more here.
- Search the Unabridged Dictionary on-line and enjoy enhanced versions of Merriam-Webster's Collegiate Dictionary and Thesaurus at Merriam-Webster Unabridged.
- A new look (and sound!) for Merriam-Webster's Word of the Day Along with a dynamic new easy-to-read format, our popular daily dose of word power now includes audio pronunciations. Subscribe today!
- One-stop shopping for the adult learner Visit ClassesUSA for a wide range of online education.

#### Pronunciation Symbols

Click on the example word to hear it pronounced.

\&\ as a and u in <u>abut</u>
\&\ as e in <u>kitten</u>
\&r\as ur/er in <u>further</u>
\a\ as a in <u>ash</u>
\A\ as a in <u>ace</u>
\a\ as o in <u>mop</u>
\au\ as ou in <u>out</u>
\ch\ as ch in <u>chin</u>

\e\ as e in <u>bet</u> \E\ as ea in <u>easy</u> \g\ as g in <u>go</u> \i\ as i in <u>hit</u> \I\ as i in <u>ice</u> \j\ as j in j<u>ob</u> \[ng]\ as **ng** in <u>sing</u> \O\ as o in <u>go</u> \o\ as aw in law \oi\ as oy in boy \th\ as th in thin \th\ as th in the \ui\ as oo in loot \ui\ as oo in foot \ui\ as y in yet \zh\ as si in vision

For more information see the Guide To Pronunciation.

Home

Link to Us

Advertising Info

Company Info

Contact Us

© 2003 by Merriam-Webster, Incorporated Merriam-Webster Privacy Policy